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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/780,296	02/17/2004	Constance Neely Wilson	5623-13	9724

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EXAMINER	
BERCH, MARK L	

ART UNIT	PAPER NUMBER
1624	

DATE MAILED: 02/06/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/780,296	WILSON ET AL.	
	Examiner	Art Unit	
	Mark L. Berch	1624	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) 1-12 is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) 1-12 is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date 4/20/05,2/17/04.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 1, 3-5 and 12 are rejected under 35 U.S.C. 102(a) as being anticipated by Foley (2003). See page 3608, column 2, compounds 14-16, which correspond to R2 = alkyl, R1 = benzyl or halobenzyl, q=1, A = phenylene, R3 = acetamido. Note that the rejected claims are not entitled to benefit of 60/448212, as these claims are broader than the broadest teaching in the priority document. For example, the claims permit a broader definition of A and of R3 than is seen in the priority document.

Claims 1, 3-5 and 12 are rejected under 35 U.S.C. 102(e) as being anticipated by Dunten. Numerous examples have 8-acetamidobenzyl, 1-optionally fluorinated benzyl, e.g. examples 1-50. Note also paragraph 617, 645, 665, 818, 824, 830, etc. The priority claim is

invalid because all of the claims are broader than the priority document.

Claims 1-7 are rejected under 35 U.S.C. 102(b) as being anticipated by Thyrion. Note that the claims as amended now permit R2=alkyl. See page 4, next to last line. This corresponds to R1=R2=methyl, q=1, A=phenyl, R3=H.

Claims 1-7, 12 are rejected under 35 U.S.C. 102(b) as being anticipated by Krantz. Note that the claims as amended now permit R2=alkyl. See Table 1, compounds 1-4. This corresponds to R1=R2=methyl, q=1, A=phenyl, R3=Halo, amino, or acetylamino.

Claims 1-7, 12 are rejected under 35 U.S.C. 102(b) as being anticipated by Suzuki. Note that the claims as amended now permit R2=alkyl. See Table 1, compounds 12. This corresponds to R1=R2=propyl, q=1, A=thiazolyl, R3=H.

Claims 1-7, 12 are rejected under 35 U.S.C. 102(b) as being anticipated by Connell. Note that the claims as amended now permit R2=alkyl. See Column 18, line 10, and Table 1, compounds VIII, XXXI and XXXII. This corresponds to R1=R2=methyl, q=1, and either A=phenyl, R3=Halo or A=thienyl, R3=H.

Claims 1-7 are rejected under 35 U.S.C. 102(b) as being anticipated by Neeley 5786360.

See Column 7, formula VI, and the definitions at lines 29-39.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-12 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

1. The definition of R1/R2 is unclear. In the first choice, i.e. the material before the semicolon at page 3 or 9, line 2, R2 is defined but R1 is not. For purposes of examination, the R1 definition from the second choice, i.e. the material after that semicolon has been used, but it is unclear whether that is actually the correct assumption.

2. For R15 and R15, the first term should be "alkylene", not alkyl.

3. It is unclear if the A of claim 4 refers to the A of Claim, second line below first formula, or the A of s last line of page 4 of 9, or both. The use of the same variable name A for two different variables introduces confusion. Likewise the A of claim 6.

4. The formula at page 5 of 9, line 6 is unclear. What is the meaning of the dashed lines? Where is the valence bond for this substituent?

5. At first line of page 6 of 9, it is unclear if the "a benzyl- or phenyl-...." refers to an additional choice for R8 or is a substituent group on the alkyl, alkenyl or alkynyl.

6. "Preferably" (in e.g. R6, R7) is improper alternative language.

7. "Substituted" (in e.g. the "substituted amino" of the R6 definition) --- with what?

Claims 1-12 rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for compound, and salts and prodrugs thereof, does not reasonably provide enablement for hydrates. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make the invention commensurate in scope with these claims.

The claims, insofar as they embrace hydrates are not enabled. The evidence of the specification is clear: The numerous examples presented all failed to produce a hydrate. These cannot be simply willed into existence. As was stated in *Morton International Inc. v. Cardinal Chemical Co.*, 28 USPQ2d 1190 "The specification purports to teach, with over fifty examples, the preparation of the claimed compounds with the required connectivity. However ... there is no evidence that such compounds exist... the examples of the '881 patent do not produce the postulated compounds... there is ... no evidence that such compounds even exist." The same circumstance appears to be true here: there is no evidence that solvates of these compounds actually exist; if they did, they would have formed. Hence, applicants must show that solvates can be made, or limit the claims accordingly.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., In re Berg, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); In re Goodman, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); In re Longi, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); In re Van Ornum, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); In re Vogel, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and In re Thorington, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1-12 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-20 of copending Application No. 10861677. Although the conflicting claims are not identical, they are not patentably distinct from each other because there is significant overlap between the two applications.

For example, the second species of claim 8 in 10780296 falls within claim 1 of 10861677, as it corresponds to Alk14=methyl, Ar=pyridyl, R16=H, r=2, R20=amino, R1=propyl, R2=H in 10861677.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Mark L. Berch whose telephone number is 571-272-0663. The examiner can normally be reached on M-F 7:15 - 3:45.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James O. Wilson can be reached on (571)272-0661. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Mark L. Berch

Primary Examiner
Art Unit 1624

1/31/06